

REMARKS

1. Amendment to the Specification

Applicants amend the Abstract by (1) deleting phrases allegedly “implied,” (2) correcting obvious grammatical errors, and (3) italicizing the Latin name of a plant family. Accordingly, no prohibited new matter is introduced by entry of the presently amended Abstract.

2. Status of the Claims

Claims 1-5 stand pending. Claims 1-5 stand rejected. Upon entry of the present amendment, claims 1-5 stand canceled. Applicants newly introduce claims 6-13 to more precisely recite the claimed subject matter. Support for the amendments can be found at least, for example, [0009], [0013], [0050], and [0052] of the Specification, as well as the originally presented claims. Accordingly, no prohibited new matter is introduced by entry of the present amendment.

Furthermore, the claims have been amended without prejudice to, or disclaimer of, the canceled subject matter. Applicants reserve the right to file a continuation or divisional application on any subject matter canceled by way of amendment.

3. Acknowledgement of Certified Priority Documents

Applicants note with appreciation the indication that the certified priority documents have been received in the present application.

4. Acknowledgement of Information Disclosure Statements

Applicants note with appreciation the acknowledgement of the Information Disclosure Statements filed August 1, 2007, and September 5, 2007.

5. Acknowledgement of Acceptable Drawings

Applicants note with appreciation the acknowledgement that the drawing filed on September 29, 2006 is accepted by the Office.

6. Objection to the Specification

The Office alleges that the Abstract contains phrases that can be implied. Office Action, page 2. Applicants amend the Abstract by deleting “The present invention provides.” Accordingly, the Office’s objection should be withdrawn.

7. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 2-5 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action, page 3. Upon entry of the present amendment, claims 2-5 stand canceled. Accordingly, the Office’s rejections should be withdrawn.

8. Objection to the Claims

The Office objects to claim 2 for informalities. Office Action, page 4. Upon entry of the present amendment, claim 2 stands canceled. Accordingly, the Office’s objection should be withdrawn.

9. Rejections of the Claims Under 35 U.S.C. § 102

9.1. Rejections Under 35 U.S.C. § 102(a)

The Office rejects claims 1-5 under 35 U.S.C. § 102(a) as allegedly being anticipated by Ogawa et al., JP 2004000171 A [“Ogawa”]. Office Action, page 5. Ogawa allegedly teaches that:

- 1) a composition comprising an extract of maca is obtained by extracting ground maca in aqueous ethanol at a temperature of about 40°C for about 72 hours;
- 2) the maca extract can be added to a food to obtain a functional food product;
- 3) uptake of the food product increases blood levels of growth hormones and improve stamina; and
- 4) the food product is effective for preventing an increase of wrinkles or gray hair and improving physical strength and reproductive function.

Claims 1-5 stand canceled upon entry of the present amendment. Applicants respectfully request withdrawn of the rejection. Furthermore, Applicants traverse the rejection to the extent it applies to the newly introduced claims 6-13.

Prior art that anticipates a claim must disclose each and every element of the claim explicitly or inherently. The fact that a certain property possibly is present in the prior art is

insufficient to establish the inherency of such a property. *See In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). For process or method claims, a new use for a known product or process is patentable, if the new use is not analogous to the known product or process. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378-79, 77 U.S.P.Q.2d 1321, 1328 (Fed. Cir. 2005). The prior art anticipates only when “the prior art necessarily functions in accordance with, or includes, the claim limitations.” *Id.* at 1375, 77 U.S.P.Q.2d at 1326 (citing *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1305 (Fed. Cir. 1999)). In the same vein, principles of inherency do not prohibit a process patent for a new use of an old or known product or process. *In re King*, 801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986).

The newly introduced claims 6-13 recite (1) a method of improving cutaneous peripheral blood flow by administering, as an active ingredient, an extract of plant belonging to the genus *Lepidium* of the family *Cruciferae*, e.g., maca, to a human subject in need thereof (claims 6-11), and (2) a method of improving skin disorders, such as frostbites, chilblains, and chaps, by administering the extract to a human subject in need thereof (claims 12-13). The disclosed maca extract in Ogawa allegedly is capable of increasing blood levels of growth hormones and improving stamina. However, neither the improvement of cutaneous peripheral blood flow nor the improvement of skin disorders *necessarily* results from any of alleged actions of Ogawa. Ogawa fails to teach administering a maca extract to a human subject in need of (1) improvement of cutaneous peripheral blood flow or (2) improvement of skin disorders, as recited in amended claims. Thus, Ogawa does not teach or suggest the present claim limitations. *See Perricone*, 77 U.S.P.Q.2d at 1328; *Rijckaert*, 28 U.S.P.Q.2d at 1957. Accordingly, the newly introduced claims 6-13 are patentable over Ogawa. Applicants respectfully request allowance of the claims.

9.2. Rejections Under 35 U.S.C. § 102(b)

The Office rejects claims 1-3 and 5 under 35 U.S.C. § 102(b) as allegedly being anticipated by Yamada, JP 2001348334 A [“Yamada”]. Office Action, page 7. Yamada allegedly teaches:

- 1) a nutritional supplement composition comprising a maca extract of 10-14%;
and

- 2) multiple actions of the nutrition supplement, such as nourishing, recovering from fatigue, strengthening, improving liver function, invigorating, ameliorating neuralgia, and ameliorating an insufficient blood circulation.

Claims 1-3 and 5 stand canceled upon entry of the present amendment. Applicants respectfully request withdrawn of the rejection. Furthermore, Applicants traverse the rejection to the extent it applies to the newly introduced claims 6-13.

First, Yamada teaches a nutrition supplement containing guarana, a maca extract placenta, pueraria, and a Kava extract, all of which are *jointly* responsible for the listed benefits. *See* Abstract of Yamada (“The nutritional supplement contains guarana, *Maca* extracts, placenta, pueraria and Kava extracts as a main active ingredient.”). For the present application, the maca extract alone is sufficient to improve cutaneous peripheral blood flow.

Second, the newly introduced claims 6-13 recite (1) a method of improving cutaneous peripheral blood flow by administering, as an active ingredient, an extract of plant belonging to the genus *Lepidium* of the family *Cruciferae*, *e.g.*, maca, to a human subject in need thereof (claims 6-11), and (2) a method of improving skin disorders, such as frostbites, chilblains, and chaps, by administering the extract to a human subject in need thereof (claims 12-13). The Office is reminded that “[c]laims must be read in view of the specification, of which they are a part.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1995). In the present application, both the improvement of cutaneous peripheral blood flow and the improvement of skin disorders are described as *local actions*, which are distinguishable from the global effects of conventional drugs to dilate blood vessels. *See* paragraphs [0002] and [0003] of the Specification. The disclosed nutrition supplement Yamada, which contains a maca extract, is allegedly capable of nourishing, recovering from fatigue, strengthening, improving liver function, invigorating, ameliorating neuralgia, and ameliorating an insufficient blood circulation. However, neither the improvement of cutaneous peripheral blood flow nor the improvement of skin disorders *necessarily* results from any of alleged actions of Yamada. Yamada fails teach administering a maca extract to a human subject in need of (1) improvement of cutaneous peripheral blood flow or (2) improvement of skin disorders, as recited in amended claims. Thus, Yamada does not teach or suggest the present claim limitations. *See Perricone*, 77 U.S.P.Q.2d at 1328; *Rijckaert*, 28 U.S.P.Q.2d at 1957. Accordingly, the newly

introduced claims 6-13 are patentable over Yamada. Applicants respectfully request allowance of the claims.

9.3. Rejections Under 35 U.S.C. § 102(e)

The Office rejects claims 1-3 and 5 under 35 U.S.C. § 102(e) as allegedly being anticipated by Zuckerman, U.S. Pub. No. 2005/0036954 A [“Zuckerman”]. Office Action, page 7. Zuckerman allegedly teaches that:

- 1) a pharmaceutical composition comprises an extract of maca as an active ingredient;
and
- 2) the disclosed composition allows inflow of blood to the penis.

Claims 1-3 and 5 stand canceled upon entry of the present amendment. Applicants respectfully request withdrawn of the rejection. Furthermore, Applicants traverse the rejection to the extent it applies to the newly introduced claims 6-13.

First, the Office mischaracterizes Zuckerman. Zuckerman teaches the inclusion of natural medicinal herbs and botanicals, such as maca, in the disclosed composition. *See* [0014], [0022], [0025], and Abstract of Zuckerman. Accordingly, Zuckerman does *not* teach an *extract* of maca.

Second, Zuckerman teaches that “[t]he natural medicinal herbs and botanicals are *selected from the group* consisting of catuaba, damiana, horny goat weed, maca and muria purma.” *See* [0014] of Zuckerman (emphasis added). This language indicates that maca is *not necessarily* present in the composition. Furthermore, the composition disclosed in Zuckerman contains “a sexual enhancement compound ... for enhancing sexual activity of the user.” *Id.* In Embodiment 1, sildenafil citrate (VIAGRATM), vardenafil hydrochloride (LEVITRATM), and tadalafil (CIALISTM) are included in the composition as the sexual enhancement compound and active ingredient. It is well known that these sexual enhancement compounds are capable of activating blood inflow to the penis. Maca, therefore, is not the active ingredient of the disclosed composition.

The newly introduced claims 6-13 recite (1) a method of improving cutaneous peripheral blood flow by administering to, as an active ingredient, an extract of plant belonging to the genus *Lepidium* of the family *Cruciferae*, e.g., maca, a human subject in need thereof (claims 6-11),

and (2) a method of improving skin disorders, such as frostbites, chilblains, and chaps, by administering the extract to a human subject in need thereof (claims 12-13). The Office is reminded that “[c]laims must be read in view of the specification, of which they are a part.” *Markman*, 34 U.S.P.Q.2d at 1329. In the present application, both the improvement of cutaneous peripheral blood flow and the improvement of skin disorders are described as *local actions* targeting the affected sites. *See* paragraphs [0002] and [0003] of the Specification. The disclosed composition in Zuckerman allegedly allows inflow of blood to the penis. However, neither the improvement of cutaneous peripheral blood flow nor the improvement of skin disorders *necessarily* results from the alleged action of Zuckerman. Zuckerman thus fails to teach administering a maca extract to a human subject in need of (1) improvement of cutaneous peripheral blood flow or (2) improvement of skin disorders, as recited in amended claims. Thus, Zuckerman does not teach or suggest the present claim limitations. *See Perricone*, 77 U.S.P.Q.2d at 1328; *Rijckaert*, 28 U.S.P.Q.2d at 1957. Accordingly, the newly introduced claims 6-13 are patentable over Zuckerman. Applicants respectfully request allowance of the claims.

CONCLUSION

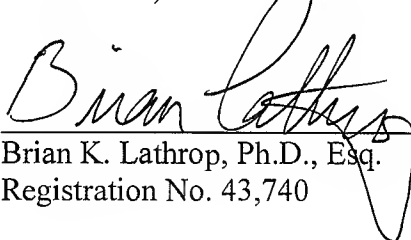
Should the Examiner have any questions or comments regarding Applicants' amendments or response, please contact Applicants' undersigned representative at (202) 842-8862. Furthermore, please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully submitted,

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